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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,019	LIZIO ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 10* is/are pending in the application.

4a) Of the above claim(s) *3 - 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 6 - 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/06; 1/5/07; 9/21/07; 12/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction

1. Applicant's election with traverse of an inner controlling layer matrix material of methyl methacrylate and ethylacrylate and a substance having a modulatory effect of succinic acid or a salt thereof in the reply filed on February 15, 2008 is acknowledged. The traversal is on the ground(s) that the burden of proof is on the Examiner to provide reasons and/or examples to support the conclusion of patentable distinction and that searching of the entire claim would not be a serious burden from the office and that in chemical cases, the same utility in a generic sense suffices as these compounds can be claimed together, the compounds should be examined together.

This is not found persuasive because the matrix materials and substance having a modulatory effect have different core structures. While some of the polymers of claim 2 comprise vinyl monomers, the proteins of 5 comprise amino acid monomers. Waxes and resins also have different chemical components. The substance having a modulatory effect is not limited in the specification and can be any compound that modulates (alters) the release rate of the drug. This could be the organic acids exemplified in the claims but also could be a controlled release polymers, an enteric-release polymers or any other excipients that alter the release rate of an active ingredient from the pharmaceutical form. This variability in core structure makes it

unclear from their very nature that all of them possess the common property that is mainly responsible for the claimed relationship.

The requirement is still deemed proper and is therefore made FINAL.

The search was not expanded beyond the elected species as art was found against the elected species.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 – 7 of copending Application No. 10/532,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2 and 4 – 7 are generic to all that is recited in claims 1 and 2 of the instant application. That is the claims of the instant application fall entirely within the scope of the claims of the copending Application or, in other words, the claims of the instant application anticipate the claims of the copending '831 application. Specifically, the claims of '831 recite a multilayer dosage form with a neutral core, an inner methacrylate copolymer layer and an outer coating of a copolymer. The claims of the instant application recite a multilayer form in which a modulating substance is embedded in a matrix, such as a methacrylate copolymer that contains an active ingredient when appropriate, an active ingredient layer that can also include a modulating substance and outer layer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1, 2 and 6 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 8 – 11 and 14 of copending Application No. 10/572,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to all that is recited in claims 1, 2, 4, 8 – 11 and 14 Application '963. That is, claim 1, 2, 4, 8 – 11 and 14 of '963 fall entirely within the scope of claims 1, 2 and 6 – 10 or, in other words, claims 1, 2 and 6 – 10 are anticipated by claims 1, 2, 4, 8 – 11 and 14 of '963. Specifically, both set of claims recite a multilayer pharmaceutical composition comprising an inner controlling layer, an active ingredient layer and an outer controlling layer and use the open language "comprising". While the claims of the instant application recite an optional neutral core, the claims of '963 require a core layer comprising a substance having a modulating effect, a pharmaceutical pellet that is encompassed by the claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 2 and 6 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6 – 9 and 11 of copending Application No. 11/815,677 in view of Noda et al. (US Patent 5,320,853).

The claims of the instant application recite a multilayer pharmaceutical pellet in which a modulatory substance is present. The claims of '677 recite a multiparticulate pharmaceutical formulation comprising pellets with a multilayer structure. The claimed structure of the pellets in '677 is encompassed by the claimed pellet formulation in the instant application.

Noda et al. discloses multilayer pharmaceutical beads (pellets; abstract). These beads can be used in a variety of pharmaceutical forms such as capsules, tablets and syrups to name a few (col 11, 7 – 12).

It would have been obvious to one of ordinary skill in the art to sue the multilayer pellets of the claims of the instant application in the multiparticulate pharmaceutical form of the claims of '677 as Noda et al. discloses that such pellets (beads) are suitable for use in dosage forms in which the pellets are used in the formation of a suitable multiparticulate pharmaceutical dosage form.

This is a provisional obviousness-type double patenting rejection.

6. Claims 1, 2 and 6 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4 and 8 – 11 of copending Application No. 11/816,372 in view of Noda et al. (US Patent 5,320,853). The claims of the instant application recite a multilayer pharmaceutical pellet in which a modulatory substance is present. The claims of '372 recite a multiparticulate pharmaceutical formulation comprising pellets with a multilayer structure. The claimed structure of the pellets in '372 is encompassed by the claimed pellet formulation in the

instant application. While the claims of '371 also require the presence of a non-neutral core that comprises a substance having a modulatory effect, the claims of the instant application use open "comprising" language so the pellet formulation of '372 falls within the scope of the claims of the instant application.

Noda et al. discloses multilayer pharmaceutical beads (pellets; abstract). These beads can be used in a variety of pharmaceutical forms such as capsules, tablets and syrups to name a few (col 11, 7 – 12).

It would have been obvious to one of ordinary skill in the art to sue the multilayer pellets of the claims of the instant application in the multiparticulate pharmaceutical form of the claims of '372 as Noda et al. discloses that such pellets (beads) are suitable for use in dosage forms in which the pellets are used in the formation of a suitable multiparticulate pharmaceutical dosage form.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 6 – 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specific examples given of substances having a modulatory effect are given but the entire genus of "substances having a modulatory effect" does not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. Applicant states that these compounds "may have a molecular weight of below 500, be in solid form and be ionic" (p 8, ln 32 – 35) but a limiting definition is not provided. Examples are provided on p 9, ln 4 – 9. The specification provides insufficient written description to support the full genus of substances having a modulatory effect beyond the specific species of succinic acid, citric acid, tartaric acid, laurylsulphuric acid, a salt of these acids or a salt of the anions taurochlolate, chlorides, acetates, lactates phosphates and sulphates. As to the term "other cholates", Applicant has not provided a description as to how the base molecule of cholate (or taurochlolate, it unclear which is the base molecule) may be changed while remaining a compound that falls within the subspecies "other cholates". The compounds encompassed by each term is diverse and the chemical structures are highly variant and encompass a myriad of possibilities. Therefore, the size of an effect a compound must exert to have a modulating effect or how closely related to a cholate a compound must be to remain a cholate is not defined in the specification.

Claim Rejections - 35 USC § 112 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 2 and 6 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what components are required to be present in the various layers of the pharmaceutical. A non-limiting definition of the term "substance having a modulatory effect" is presented in the specification. Almost any ingredient present in a pharmaceutical formulation could modulate the release rate of the active ingredient. The components required to be present in each layer are also vague and indefinite because of the use of the phrase "where appropriate" in layers b) and c). The specification provides no guidance as to when it would be appropriate to add an active ingredient to the b) layer comprising a substance having a modulatory effect and when it would be appropriate to add a substance having a modulatory effect to the c) layer comprising an active pharmaceutical ingredient.

10. Claims 1, 2 and 6 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether layer c) must be a separate layer from layer b) and layer d). Particularly when an active ingredient is present in layer b) and a substance having a modulatory effect is present in layer c), the

components present in layers b) and c) would be identical and therefore layers b) and c) could be the same composition but if they contain the same composition, must they be applied in multiple steps or can one layer be applied in one step with the same compositions to meet the limitations for both the b) and c) layers. It is therefore unclear how many layers of different composition need be present in the claimed multilayer pharmaceutical form.

11. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant is intending to claim the full genus other rather the particular trademarked species of that polymer. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86

USPQ 481 (Bd. App. 1949). For example, KOLLIDON® VA64 is one particularly type of polyvinyl acetate phthalate. It is unclear whether Applicant is claiming all polyvinyl acetate phthalate polymers or the particular species of KOLLIDON® VA64. The broad limitation "celluloses" is also claimed, followed by

If the particular trademark is being claim, the item being claimed is also vague and indefinite. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves.

12. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "such as" and "for example" render the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

13. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner was unable to find the "taurochlolate" anion in

the literature to determine the structure of this anion. It is therefore unclear what substance having a modulatory effect is being described.

14. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation “a manner known per se”, and the claim also recites “spraying processes” and “fluidized bed granulation” which are narrower statements of the means by which the multilayer pharmaceutical form is made.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 2 and 6 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Panoz et al.

Panoz et al. discloses a multilayer pharmaceutical pellets comprising a core of active ingredient and an organic acid embedded in a polymeric matrix in a multi-layer arrangement and an outer membrane which allows for the release of the active ingredient in an aqueous medium (abstract).

In example 2 (col 4, ln 65 – col 5, ln 37), a polymer solution comprised of EUDRAGIT® RS was used to dampen starch/sugar seeds (neutral core) so that a powder formulation comprised of active ingredient (theophylline) and tartaric acid (an ionogenic, water-soluble organic acid substance having a modulatory effect) would adhere to and dry on the dampened seeds. This process was repeated until all of the active ingredient with organic acid powder was coated onto the seeds. EUDRAGIT® RS is a polymer comprised of 65 wt% methyl methacrylate, 30 wt% ethyl acrylate and 5 wt% methacrylate monomer with quaternary ammonium groups (p 19, ln 16 – 19 of the instant specification) and therefore meets the limitations for the matrix of the inner layer

b). In this case, both the inner controlling layer and active ingredient layer have the same composition. After application of the active ingredient powder, an outer coating comprised of EUDRAGIT® RL and RS polymers was applied. Both of these polymers are copolymers as required in layer d) (see p 19 ln 16 – 19 and 30 – 33 of the instant specification). These pellets are produce in a conventional coating pan process and therefore are made by a method known per se in the art as required in claim 10.

17. Claims 1, 2 and 6 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al. (US Patent 5,320,853).

Noda et al. discloses a controlled release pharmaceutical bead with a multi-layer core and multi-layer periphery. The core contains at least an inner portion having a suitable organic acid and a sustainably-acid-releasing coating while the periphery contains at least an inner portion with an active ingredient and sustainably-drug-releasing exterior coating (col 1, ln 65 – col 2, ln 10). The suitable acid component can be succinic acid (col 2, ln 39 – 40) which can be coated onto a substantially inert seed (neutral core; col 2, ln 41 – 43). Polymers based on acrylates and/or methyacrylates such as those sold under the trademark EUDRAGIT® are suitable for the sustainably-drug releasing exterior layer (col 2, ln 51 – 55). In the multi-layer core in example 11 (col 18, ln 14 onward), a sugar-starch core was used in conjunction with succinic acid as the suitable organic acid and hydroxypropyl methyl cellulose as the sustainably-acid releasing coating. In the multi-layer periphery, EUDRAGIT® RS was used as the

sustainably-drug-releasing coating. EUDRAGIT® RS meets the limitations on the polymers provided in layer d).

These pellets were made by a process involving the spraying of the binder on the beads (col 18, ln 28 – 32) and therefore the limitation of claim 10 is met by the prior art as spraying process is used in the method of producing the multilayer pharmaceutical formulation.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1, 2 and 6 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panoz et al.

As discussed above, Panoz et al. discloses a multilayer pharmaceutical pellet comprising a core of active ingredient and an organic acid embedded in a polymeric matrix in a multi-layer arrangement and an outer membrane which allows for the release of the active ingredient in an aqueous medium. In example 2, a multilayer pellet comprised of EUDRAGIT® RS polymers, an active agent and the substance having a modulatory effect of tartartic acid is disclosed. In this multilayer pellet formulation, the composition of the inner controlling layer and the active ingredient layer are identical.

In example 3 (col 5, ln 39 – col 6, ln 42), a polymer solution comprised of polyvinylpyrrolidone was used to dampen starch/sugar seeds so that a powder formulation comprised of active ingredient and succinic acid (an ionogenic, water-soluble organic acid substance having a modulatory effect) would adhere to and dry on the dampened seeds. This process was repeated until all of the active ingredient with

organic acid powder was coated onto the seeds. After application of the of the active ingredient powder, an outer coating comprised of polyvinylpyrrolidone and shellac.

Panoz et al. does not exemplify a composition in which methyl methacrylate and ethyl acrylate polymers with a quaternary group in the alkyl radical, an active agent and citric acid are made into a multilayer pellet.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare such a formulation as such compositions are taught, but not exemplified by Panoz et al. Substitution of tartaric acid with citric acid, taught as functional equivalents (col 2, ln 42 – 45), in the composition of example 2 or substitution of polyvinylpyrrolidone with the EUDRAGIT® polymers, also taught as functional equivalents (col 2, ln 56 – 68), in the composition of example 3 both result in the composition of the elected species of the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW